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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Kenji Sunagawa

KUP-6

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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT

PAPER NUMBER

3762

NOTIFICATION DATE

DELIVERY MODE

12/01/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/523,538	Applicant(s) SUNAGAWA, KENJI	
	Examiner MICHAEL KAHRELIN	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13, 19 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/16/2010 has been entered.

Claim Objections

2. Claim 20 is objected to because of the following informalities: the claim lacks a status identifier. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 13, 19, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In regards to claims 13 and 19, the clause "wherein the pacemaker is designed such that information sent from other pacemakers implanted into the heart is input into the control unit" is vague because it is unclear what element inputs this information into the control unit, as no element has been set forth to receive information sent from other pacemakers. The examiner is considering this to be the "receiving means...transmitted from outside" element, but consistent terminology

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should be used. Furthermore, in regards to claims 13 and 19, it is unclear whether the claims require "other pacemakers." Applicant's remarks appear to indicate the intention that the claims do require additional pacemakers, and that this differentiates the claimed subject matter from the prior art (see "Remarks," pages 7-8), but because the claims recite "[a]n ultra miniature integrated cardiac pacemaker" (singular) and the claims lack a positive recitation of any elements besides this single pacemaker, the examiner is interpreting the claims to not require or recite additional pacemakers. As such, the examiner is interpreting the abovementioned clause as limiting a control unit capable of receiving signals from "other pacemakers" -- in other words, a limitation on a control unit capable of receiving a certain type of signal, and not a limitation requiring a certain source of the signal. Should Applicant wish the claims to require multiple pacemakers, it is respectfully suggested to recite a system comprising multiple pacemakers.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 13, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujii et al. (US 5,411,535, hereinafter "Fujii") in view of Heller (US 6,294,281, hereinafter "Heller"). Fujii discloses the essential features of the claimed invention, including a pacemaker (Fig. 8) having a control unit (122), a heart stimulating means (125 and 135), an electrocardiograph information detecting means (136), a transmitting

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means (137); a receiving means (123); and a power unit (139); wherein the pacemaker is capable of implantation with the tip of a catheter and requiring no chest incision (Figs. 9 and 10); wherein the pacemaker is designed such that information sent from other pacemakers implanted into the heart is input into the control unit (col. 7, line 66 to col. 8, line 1 and col. 5, lines 52-60 -- the pacemaker 150/120 explicitly receives information directly from pacemaker 100 and indirectly from pacemaker 110, and additionally and alternatively the information received by pacemaker 150/120 is *of a type that could be sent* by other pacemakers (other pacemakers are not positively recited)); wherein the control unit outputs the control signal based on information sent from other pacemakers (105) and electrocardiographic information (col. 7, lines 56-66); wherein the control unit includes a stimulation timing determining means and stimulation timing changing means (122 -- the stimulation timing changes with the received signal 105) and changes the stimulation timing when certain conditions are fulfilled (col. 8, lines 32-47 -- when the main unit modifies the pulse pattern). Fujii does not disclose that the power unit is a biological fuel cell that extracts electrons from oxidative reactions of biological fuels composed of an anode and cathode; wherein the anode is coated with immobile layer of mediators and oxidative enzymes for biological fuels, wherein the layer prevents oxygen existing in a biological body from contacting the anode, and a cathode electrode composed of a catalyst coated with a material capable of preventing permeation of reactive substances other than oxygen and allowing permeation of oxygen and hydrogen ions; wherein the fuel cell uses blood or body fluid as an electrolyte solution and utilizes biological fuels and oxygen in the blood or body fluid without the need for a

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container to contain the electrolyte solution or metabolic product; and wherein the anode and cathode contact the electrolyte solution. Heller teaches a biological fuel cell for use with implantable pacemaker devices (col. 2, lines 60-67) that extracts electrons from oxidative reactions of biological fuels composed of an anode and a cathode (col. 3, line 22 -- the spacer elements are optional); wherein the anode is coated with an immobile layer of mediators (redox polymer layer; cols. 5-9) and oxidative enzymes for biological fuels (cols. 9-12), wherein the layer prevents oxygen existing in a biological body from contacting the anode (col. 8, line 16; "poly(acrylic) acid"), and a cathode electrode composed of a catalyst (col. 3, lines 44-46 and col. 4, line 29) coated with a material capable of preventing permeation of reactive substances other than oxygen and allowing permeation of oxygen and hydrogen ions (col. 13, lines 21-47 and col. 14, lines 4-18); wherein the fuel cell uses blood or body fluid as an electrolyte solution and utilizes biological fuels and oxygen in the blood or body fluid without the need for a container to contain the electrolyte solution or metabolic product (col. 14, lines 35-43 and Fig. 1); and wherein the anode and cathode contact the electrolyte solution (col. 14, lines 35-43) to provide the predictable results of powering an implantable device without the need for replacing or recharging batteries. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Fujii's invention by providing a biological fuel cell for use with implantable devices that extracts electrons from oxidative reactions of biological fuels consisting of an anode and cathode; wherein the anode is coated with immobile layer of mediators and oxidative enzymes for biological fuels, wherein the layer prevents oxygen existing in a biological

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body from contacting the anode, and a cathode electrode coated with a material capable of preventing permeation of reactive substances other than oxygen and allowing permeation of oxygen and hydrogen ions; wherein the fuel cell uses blood or body fluid as an electrolyte solution and utilizes biological fuels and oxygen in the blood or body fluid; and wherein the anode and cathode contact the electrolyte solution to provide the predictable results of powering an implantable device without the need for replacing or recharging batteries. Please note that Heller's coating material (poly(acrylic) acid) inherently prevents oxygen existing in a biological body from contacting the anode. See Reichert et al. (US 5,270,128; col. 3, lines 40-65) as evidence of inherency. In the alternative, it is notorious in the fuel cell arts to prevent oxygen from contacting anodes to provide the predictable result of avoiding degradation of the anode material. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify Fujii's invention by preventing oxygen from contacting the anode to provide the predictable result of avoiding degradation of the anode material.

Response to Arguments

7. Applicant's arguments filed 11/16/2010 have been fully considered but they are not persuasive. Applicant argued that Fujii fails to disclose other pacemakers or receiving information from other pacemakers in the heart. However, the claims do not recite additional pacemakers, but only a single pacemaker with a control unit with the capability of receiving information of a type that could be sent by other pacemakers. The examiner respectfully submits that even if Fujii's elements 100 and 110 were not

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pacemakers (which the examiner does not concede, but asserts that Fujii discloses that both of these elements are pacemakers at, e.g., col. 7, line 68 and col. 5, lines 54-60), that the signal received by Fujii's element 150 (105) is of a type that could be sent by a pacemaker. The second "wherein" clauses of claims 13 and 19 cannot possibly limit additional pacemaker elements because only a single pacemaker is recited in the claims. As such, this limitation limits only the receiving means and control unit of the single pacemaker set forth. The examiner maintains that Fujii's element 150 is capable of receiving "information sent from other pacemakers" because it can receive signal 105 ("pulse signal"). The ability of element 150 to receive this pulse signal is unaffected by whether the element sending the signal also delivers electrical therapy.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHRELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/
Primary Examiner, Art Unit 3762